EUROPEAN UNION ENLARGEMENT: EXPORT OPPORTUNITIES FOR U.S. SMALL AND MEDIUM-SIZED COMPANIES

CE MARKING – YOUR PASSPORT TO CENTRAL AND EASTERN EUROPE

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PREFACE

On May 1, 2004, the European Union (EU) will expand from 15 countries to 25. Eight of these New Member States -- the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, the Slovak Republic, and Slovenia -- are located in Central and Eastern Europe. This report focuses on the adoption of the CE Marking system by the Central and Eastern European countries of the Slovak Republic, Hungary and Poland. Currently over 50 percent of U.S. products exported to the EU require the mandatory CE Marking. This report will provide U.S. small and medium–sized enterprises (SMEs) an overview of the CE Marking process; the steps required to obtain CE Marking; and progress made by the Slovak Republic, Hungary, and Poland in implementing and carrying out the CE Marking regime.

This report is based on market research and analysis undertaken in June and July 2003 in Belgium, the Slovak Republic, Hungary, and Poland by Indrek Grabbi, International Trade Specialist, and Margaret Donnelly, Team Leader in the Commerce Department's, Office of Microelectronics, Medical Equipment, and Instrumentation. Mr. Grabbi and Mrs. Donnelly interviewed European Commission Officials, in Brussels, Belgium and government officials, national standards bodies, certification and testing labs, representatives of U.S. companies, and local U.S. Chambers of Commerce in Bratislava, the Slovak Republic; Budapest, Hungary; and Warsaw, Poland. U.S. Commercial Service (USCS) market specialists in the respective countries attended these interviews and actively supported this work. The author supplemented information gathered from on-site interviews with available market research.

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This report is intended to provide general guidance for U.S. exporters and does not constitute legal advice.

EXECUTIVE SUMMARY

On May 1, 2004 the European Union will grow to 25 Member States with a population of 450 million and a GDP of \$12 trillion. The enlarged EU will account for 19 percent of world trade. Ten countries -- the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic, and Slovenia -- will accede to the European Union on May 1, 2004. This expansion presents an unparalleled opportunity for U.S. companies doing business or wanting to do business in the enlarged European Union. – the largest single market in the world.

Exporting to the New Member States upon accession will clearly become less burdensome and more streamlined since there will be one set of EU standards and rules to follow. The greatest benefit of EU enlargement to U.S. companies will be that a single set of trade rules will apply to the ten new Member States. Multiple sets of disparate national standards and regulations will be harmonized to one set of New Approach Directives covering over 50 percent of U.S. products currently exported to the EU. The CE marking system will be adopted by all ten new Member States. The CE marking system established one set of regulations that, once met, allowed goods to move freely in Europe. All manufacturers in the EU and abroad must affix the CE Marking to those products covered in the New Approach Directives. Once a company has met the CE Marking requirements for its products it can market these products throughout the expanded EU without having to make separate product modifications for each Member State. CE Marking is known as the "passport" to the free circulation of products within the EU. A product with valid CE Marking should be accepted as readily in the Slovak Republic as well as in Estonia or in Germany or France.

The enforcement of the CE Marking system is carried out by each individual Member State. Market surveillance is an important tool for enforcing New Approach Directives. Each New Member State will establish its own market surveillance infrastructure. As a result, the legal and administrative market surveillance infrastructures differ from one Member State to another. Market surveillance is carried out by the Member States' Departments of Industry, Labor, Trade, Health, and sometimes even by Customs authorities.

The European Commission in Brussels and the New Member States have been working for several years to integrate their varied trading systems into one common market. This pre-accession process has been long and difficult and is not yet finished. Each New Member State must interpret, implement, and enforce the New Approach Directives – otherwise know as the CE Marking system – into their respective economies. The European Commission has been working with the New Member States to ensure that the CE Marking system will be uniform throughout the entire expanded EU and that goods will flow freely within the internal market.

The Slovak Republic, Hungary, and Poland will all accede to the European Union on May 1, 2004. Each of the three countries will be in various degrees of readiness to implement and enforce the CE Marking system.

Hungary is the furthest along in the implementation and enforcement of the CE Marking system. Hungary will accept some CE marked products prior to accession. U.S. products with valid CE Marking can enter Hungary now in the following seven industrial sectors without further testing or certification requirements -- electrical safety, electromagnetic compatibility, gas appliances, medicinal products for human use, hot water boilers, explosion proof equipment, and medical devices. U.S. exporters of products with valid CE Marking in all other sectors must obtain a Hungarian "H" mark until May 1, 2004. CE Marking enforcement and market surveillance is primarily carried out by the State Office for Consumer Protection; Hungarian customs may also check for CE Marking.

The Slovak Republic lags behind Hungary in the implementation of the CE Marking system. U.S. products with valid CE Marking can enter the Slovak Republic now in the following industrial sectors without further testing or certification requirements -- machinery, electromagnetic compatibility, explosive atmosphere equipment, personal protective equipment, and electrical safety. U.S. exporters of products with valid CE Marking in all other sectors should obtain an approval certificate stating that their products meet Slovak standards until May 1, 2004. CE Marking enforcement is carried out by the Trade Inspectorate and market surveillance is carried out by customs for goods entering the EU through the Slovak Republic.

Poland lags behind both Hungary and the Slovak Republic in the implementation of the CE Marking system. Poland is slowly harmonizing its standards, certification, and testing procedures to EU norms. Currently, U.S. exporters to Poland, whether they have the CE Marking or not, are required to obtain a "B" Certificate for safety to clear customs; 1,400 different products require the "B" mark certificate. When Poland joins the EU, Polish customs will check for CE Marking and the Office of Consumer Protection will be responsible for market surveillance and enforcement of CE Marking.

Upon accession – May 1, 2004 -- Hungary, the Slovak Republic, and Poland will no longer require U.S. products with valid CE Marking to undergo further national testing and certification requirements. A U.S. exporter with valid CE Marking should be able to export its products to Central and Eastern Europe as easily as it does to the current EU Member States.

OVERVIEW OF EU ACCESSION

The accession of eight Central and East European nations – the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, the Slovak Republic, and Slovenia – plus Malta and Cyprus – into the EU on May 1, 2004 presents an unparalleled opportunity for U.S. companies doing business or wanting to do business in the enlarged European Union. On May 1, 2004, the EU will have 25 Member States and a population of 450 million. Central and East European accession will further add 75 million people to the EU marketplace, increasing overall buying power; creating a demand for high-end technology; and the need for more competitive and efficient means of production.

EU membership requirements have pushed market liberalization in the ten accession countries. The current European Union is already the largest single market in the world. In economic terms, with enlargement the EU-25 will account for 19 percent of world trade. EU enlargement will: increase prosperity in the new Member States; accelerate growth rates; and give direct access to an enlarged EU market for U.S. companies.

The greatest benefit of EU enlargement to U.S. companies will be that a single set of trade rules will apply to the ten new Member States. In addition, U.S. companies will face a single tariff rate in all Member States and a single set of administrative procedures will apply to all 25 members. There will be no internal border checks between the Member States and the harmonization of standards and regulations will enhance free trade within the single market. In practical terms, this will mean that once the products of U.S. exporters comply with the health and safety requirements of Hungary, those goods can also be sold on the French or German markets, because the same set of rules apply across the entire EU market. In essence the ten new Member States will adopt the common commercial policy of the European Union in its entirety upon accession.

CE MARKING AS YOUR PASSPORT TO CENTRAL AND EASTERN EUROPE

CE Marking & the European Union

CE Marking is a symbol that the European Union requires on over 50 percent of U.S. products exported to the EU. The CE Marking system was established to safeguard public health, by ensuring that a specific product complies with the European product safety, health and environmental requirements.

The European Commission describes CE Marking as a "passport" that allows manufacturers to circulate industrial products freely within the internal market of the EU. Before the CE Marking system was developed, U.S. exporters to Europe, as well as domestic European suppliers, had to comply with multiple, and often inconsistent, sets of

national regulatory requirements. The CE Marking system established one set of regulations that, once met, allowed goods to move freely in Europe. All manufacturers in the EU and abroad must affix the CE Marking to those products covered by the New Approach Directives. The CE Marking on a product indicates to EU authorities that the product complies with the essential requirements of all Directives that apply to it. Once a company has met the CE Marking requirements for its products it can market these products throughout Europe without having to make separate product modifications for each Member State.

The CE Marking system covers the fifteen countries of the European Union – Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and the United Kingdom – and the European Free Trade Association (EFTA) countries of Iceland, Liechtenstein, and Norway. CE Marking will come into force in the New Member States, upon accession, on May 1, 2004.

Products Requiring CE Marking

The CE Marking is mandatory for products covered by the 22 New Approach Directives:

Machinery	Medical devices
Low voltage equipment	In vitro medical devices
Electromagnetic compatibility	Active implantable medical devices
Explosive atmosphere equipment	Personal protective equipment
Explosives for civil use	Hot water boilers
Noise emissions	Gas appliances
Radio & Telecom terminal equipment	Refrigeration appliances
Non-automatic weighing equipment	Toys
Simple pressure vessels	Lifts
Pressure equipment	Recreational craft
Construction products	Cableway installations for passengers

For a complete list of New Approach Directives and related standards, please visit: http://www.newapproach.org. The U.S. Department of Commerce's National Institute of Standards and Technology (NIST) provides EU Directives publications at the following web site: http://ts.nist.gov/ts/htdocs/210/gsig/europe.htm. The U.S. Department of Commerce also maintains information on CE Marking at: http://www.ita.doc.gov/td/tic/ce_mark/ceindex1.htm

Organization of the CE Marking System

Generally, each New Approach Directive contains:

- A definition of the products covered by the directive.
- A set of essential requirements that the product must meet.
- The procedures needed to establish compliance.

The New Approach Directives do not contain the technical specifications needed to manufacture a product that will comply with the essential requirements listed in each of the Directives. A manufacturer has the option to rely on product standards to show that a product meets the underlying essential requirements of the Directive. Use of European harmonized standards (HS standards), although voluntary, provides for a presumption of conformity. This means your products will be presumed to be in conformity with the essential requirements set forth in the Directives. By opting not to use harmonized standards, the manufacturer has to provide detailed proof showing how the product meets the essential requirements. The manufacturer is always responsible for conformity. The burden can be shifted in exceptional cases, when for instance, the distributor agrees to handle CE marking because he needs to assemble the product and have it tested as a complete unit.

There are three recognized EU standards development organizations responsible for creating European harmonized standards:

- The European Committee for Standardization (CEN) http://www.cenorm.be/cenorm/index.htm
- The European Committee for Electrotechnical Standardization (CENELEC) http://www.cenelec.org/Cenelec/Homepage.htm
- The European Telecommunications Institute (ETSI) http://www.etsi.org/

EU standards may be purchased in the EU from national standards organizations and in the U.S. from the American National Standards Institute (ANSI). ANSI is a private non-profit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system. For information about ANSI, please visit their web site: http://www.ansi.org/default.aspx. EU standards may also be purchased from trade associations and various other private companies. Standards cost generally between \$20 and \$125 per standard depending on the number of pages.

For most products, a manufacturer may self-declare compliance with the appropriate Directive(s). However, this may require the services of an outside testing laboratory to document product performance.

For some classes of products, as defined in the Directives, the manufacturer must have the product design and a sample product, performance or production quality assurance system approved by a European Notified Body or by a sub-contractor of a European Notified Body in the U.S., such as Underwriter's Laboratory, Inc., (UL), or KEMA, Inc. A Notified Body is an independent laboratory or testing house that has been authorized by a Member State to perform the conformity assessment in that country for a particular type of product or Directive. Manufacturers or exporters may choose any Notified Body in any EU Member State. For a current list of Notified Bodies, please visit:

http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified-bodies.htm

Enforcement of the CE Marking system is carried out by each individual Member State. Market surveillance is an important tool for enforcing New Approach Directives, in particular by taking measures to check that products meet the essential requirements of the applicable Directives, that action is taken to bring non-compliant products into compliance, and that sanctions are applied when necessary. Each Member State must establish its own market surveillance infrastructure. As a result, the legal and administrative market surveillance infrastructures differ from one Member State to another.

Market surveillance authorities have the power to regularly visit commercial, industrial and storage premises; to regularly visit, if appropriate, work places and other premises where products are put into service and to organize random spot checks. Market surveillance is carried out by the Member States' Departments of Industry, Labor, Health, and sometimes even by Customs authorities. The surveillance authority may require access to the manufacturer's declaration of conformity and technical file in an incident or random check.

The manufacturer, his authorized representative, or importer must be able to provide the technical file within seven to ten days from the request of the surveillance authority. If the product is found to be non-compliant, corrective action will depend on and be appropriate to the level of non-compliance. Member States can and have been known to conduct random checks on products to see if they have met CE Marking requirements.

Steps Generally Necessary to Obtain the CE Marking

- Identify the Directive(s) that are applicable to the product.
- Ensure the product complies with all essential requirements of the Directive(s).
- Identify the conformity assessment procedure. This could be self-certification, involve testing, inspection or quality assessment from a Notified Body or a combination of these. The conformity assessment will differ depending on the product and the Directive. All this information is contained in the applicable Directive(s).
- Identify any Harmonized European Standards applicable to the product. In some cases, the harmonized standards have not been developed for the product. In this case, other standards may be used to guarantee the safety of the product.
- Have the product tested for compliance with the standards by a European accredited testing laboratory, if necessary.
- Identify whether independent assessment of the product's conformity to the Directive is required from a Notified Body. This is stated in the Directive and is dependent upon the product. The conformity assessment procedure that covers the product will be specified in the Directive(s).
- Develop a technical file that documents product design, application of relevant Directives and standards and how the product meets these requirements.

- Make sure that the Declaration of Conformity identifies the product, the applicable Directives and standards, and the name of the Notified Body if required by the directive along with the manufacturers name and address.
- Authorize a representative physically located in the EU, in the case of medical devices. The authorized representative holds the technical file and Declaration of Conformity for ten years after production of the product. The surveillance authorities will contact the authorized representative if any questions arise about CE Marking compliance.
- Check that no other purely national requirements exist in the countries where the product will be sold. These may include national standards, labeling or packing requirements
- Affix the CE Marking to the product and/or its packaging and accompanying literature as stated in the Directive.

Integration of CE Marking in the New Member States of Central & Eastern Europe

One of the goals of EU accession is the free movement of goods within the expanded EU. The European Commission in Brussels and the New Member States have been working for several years to integrate their varied trading systems into one common market. This pre-accession process has been long and difficult and is not yet finished. Each New Member State must interpret, implement, and enforce the New Approach Directives – otherwise known as the CE Marking system – into their respective national economies. Although each Member State is supposed to translate the New Approach Directives into their official language without changing the substance of the directive, some variations do occur. Problems may arise because each New Member State could interpret and implement the CE Marking Directives in a slightly different fashion -- as sometimes happens with the current makeup of the European Union. However, the European Commission (EC) has thoroughly reviewed the New Directives as they have been translated in each of the New Member States to assure that the New Member States are fully complying with the Directives and that goods will flow freely on the internal market.

The New Approach Directives have a built-in mechanism to restrict or forbid the placing on the market, or the recall, of a product that poses a danger to the Member States – this mechanism is known as the safeguard clause. For a Member State to invoke the safeguard clause a product must be CE marked and ascertained by a Member State's competent national authority to present a substantial hazard. The Member State must notify the European Commission immediately after invoking the safeguard clause. The necessary evidence and information to justify the action must accompany the notification. If the European Commission considers the national action to be justified, it informs the other Member States. This action ensures an equal level of protection throughout the Community.

Implementation & Enforcement of CE Marking in the Slovak Republic

The Slovak Republic will become a member of the European Union on May 1, 2004. By this date the Slovak Republic will have transposed and implemented all EU New Approach Directives into national law. In other words, all Slovak safety requirements will be harmonized with EU New Approach Directives. In the interim the Slovak Government has signed the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (PECA) with the European Commission.

The PECA is a trade agreement that extends the EU Single Market by eliminating national barriers to trade and is at the same time an important pre-accession tool. The PECA allows a gradual market expansion in specific sectors that would lay the foundation and help the accession countries develop a process for implementing the New Approach Directives. The PECA provides for the mutual recognition of conformity assessment results, such as self-declaration and type examination that are crucial to companies receiving the CE Marking. Once a PECA is signed, the Member States help the Accession Country to implement the New Approach Directives in those sectors covered in the PECA. Horizontal laws are verified; and an assessment is made of market surveillance, Notified Bodies and standardization. As part of the signed PECA, CE Marking is recognized for the sectors covered prior to accession, and Notified Bodies can be appointed by the new Member State. A PECA helps to ensure that a New Member State's standardization, conformity assessment and accreditation are generally in line with current EU norms.

The Slovak Republic has signed a PECA covering the following New Approach Directives: machinery, electromagnetic compatibility, explosive atmosphere equipment, personal protective equipment, and electrical safety. This means the Slovak Republic fully accepts U.S. products in the aforementioned sectors with a valid CE Marking. U.S. exporters of these products can enter the Slovak market without undergoing any additional testing. The Medical Device and In Vitro Diagnostic Directives were not covered in the PECA. The signed PECA provides the European Commission with confidence that the Slovak Republic can meet all of its obligations concerning the New Approach Directives and in implementing the CE Marking system. The PECA entered into force on July 1, 2003.

CE Marking is enforced in the Slovak Republic by the Trade Inspectorate http://www.nisk.sk/main.php?doc=first.php. Market surveillance is carried out by Customs for goods entering the EU through the Slovak Republic and by the Slovak Trade Inspectorate for goods manufactured and sold in the Slovak Republic. The Slovak Office of Standards, Metrology and Testing is the competent body for standardization; their web site contains a listing of Notified Bodies and National Testing Centers: http://www.normoff.gov.sk/unms_sr/index.html The Slovak Institute for Standards is the official standards body in the Slovak Republic and is a member of the European Standards Organization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the International Standards Organization (ISO). Their web site is located at: http://www.sutn.gov.sk/en/index2.html.

U.S. exporters to the Slovak Republic of products with CE Marking not covered by the PECA should obtain an approval certificate stating that their products meet Slovak standards before the product can be cleared through customs

The certification process begins when the importer fills out an application form supplied by a Slovak National Testing Center (NTC). The application form becomes the actual certification document once it has been approved by the appropriate NTC and UNMS and has the SK 1000 marking. Substantial documentation may need to be supplied to the NTC to prove compliance with applicable product standards.

Certification of a product is carried out by a National Testing Center only if the product falls within the center's competence. The applicant is required to state the technical standards, technical documents or regulations according to which the product is to be certified. If certification is to be carried out according to foreign technical standards, technical documents or regulations, the applicant must submit copies to the NTC together with the application for certification. A U.S. company's technical file can be in English, however, the instruction manual and product label must be in the Slovak language.

U.S. companies may obtain the complete list of products requiring obligatory certification, as well as contact addresses of National Testing Centers from the Slovak Office of Standards, Metrology and Testing:

http://www.normoff.gov.sk/unms sr/index.html. For complete information please contact

http://www.normoff.gov.sk/unms_sr/index.html. For complete information please contact the U.S. Department of Commerce Foreign Commercial Service office in Bratislava: http://www.buyusa.gov/slovakia/en/.

Upon accession -- May 1, 2004 – the Slovak Republic will adopt EU standards and all U.S. products with valid CE Marking will be allowed to enter the Slovak Republic without further testing and certification.

Implementation & Enforcement of CE Marking in Hungary:

Hungary will become a member of the European Union on May 1, 2004. The Hungarian Standards Board http://www.mszt.hu/ is responsible for implementation of European and international standards as well as national standards. The Board has exclusive rights to issue and/or withdraw national standards, including development, reconciliation and publication of Hungarian national standards. The Hungarian Standards Board has harmonized most Hungarian standards to comply with the New Approach Directives issued by the European Commission. The Hungarian Standards Board is a member of CEN, CENELEC, ISO, and IEC.

The PECA signed by Hungary and the European Union entered into force on July 1, 2001. On the basis of this PECA each market accepts testing by each other's testing/notified bodies. The agreement affects products of seven industrial areas – electrical safety, electromagnetic compatibility, gas appliances, medicinal products for human use, hot water boilers, explosion proof equipment, and medical devices. Since November 1, 2003 the PECA applies to U.S. products as well; the rule of origin clause

that treated U.S. products differently from EU products has been removed. This means that Hungary fully accepts U.S. products in the aforementioned seven industrial sectors with a valid CE Marking. U.S. exporters of these products can enter the Hungarian market without undergoing any additional testing.

U.S. exporters to Hungary of products with CE Marking not covered by the PECA should obtain an "H" mark by the relevant institute in Hungary. For further information please contact the U.S. Department of Commerce Foreign Commercial Service office in Budapest: http://www.buyusa.gov/hungary/en/.

Upon accession to the EU on May 1, 2004 U.S. products with a valid CE Marking will be able to enter the Hungarian market as easily and circulate as freely as they currently enter any other EU Member State. Although, a U.S. company's technical file can be in English, the product's instruction manual and labeling must be in Hungarian.

CE Marking enforcement and market surveillance is primarily carried out by the State Office for Consumer Protection; Hungarian customs may also check for CE Marking. For a listing of Notified Bodies and testing labs please visit The Hungarian Accreditation Board's web site: http://www.nat.hu/.

Implementation & Enforcement of CE Marking in Poland

Upon accession Poland will adopt and enforce EU standards and regulations. The main objective of Poland's standardization policy is the harmonization of standards, certification, and testing procedures to EU norms. Since Poland has not signed a PECA with the EU it is far behind Hungary and the Slovak Republic in harmonizing to EU norms and adopting the New Approach Directives as well as mutually recognizing testing by each other's testing/notified bodies. Poland will not sign a PECA agreement with the EU prior to accession.

In the mean time, Poland is enforcing its own extensive system of standards and certification procedures. Originally not harmonized with international product standards, Poland has been gradually adjusting to the European Union system of certification. Polish standards have been developed over the years by a central institution, the Polish Standards Committee (PKN) http://www.pkn.pl/. The main goal of PKN is to become a member of CEN and CENELEC – which are the two main standards setting bodies for the EU. Poland's Standardization Law provides the foundation for moving forward toward a system based on self-certification and greater harmonization with EU standards. Most of PKN's recent work has been on reviewing Polish standards and harmonizing them with EU standards.

Until accession, U.S. exporters to Poland, whether they have the CE Marking or not, are required to obtain a "B" Certificate for safety to clear customs; 1,400 different products require the "B" mark certificate. Testing for the "B" mark is performed by the Polish Certificate and Testing Center http://www.pcbc.gov.pl/ and its 15 specialized institutes. These are accredited institutions that certify products. The Polish testing and certification

process is often cumbersome, complex, and time consuming. All non-EU products need to be certified and tested in Poland – EU products with CE Marking only need a verification certificate from Polish authorities to clear customs, no product testing is required in Poland. The certification and testing process takes about two months, with a maximum cost of \$2,000.

The Polish Certificate and Testing Center and its 15 specialized institutes are accredited to certify for the Polish "B" mark. These institutes need to be authorized by the appropriate government administration offices (i.e. Ministries) to perform testing in accordance with a given Directive. When authorized, they need to be registered with the EU to become Notified Bodies. This is not going to occur automatically after Poland joins the EU. Currently there are no Polish Notified Bodies, but there are Polish branch offices of Notified Bodies from the other EU countries.

Upon accession the "B" mark certification and testing process will no longer be required., although a U.S. company may want to get a voluntary "B" mark for marketing purposes. Poland will adopt EU standards and all U.S. products with correct CE Marking will be allowed to enter Poland without further testing and certification. Polish customs will check for CE Marking and the Office of Consumer Protection will be responsible for market surveillance and enforcement. U.S. products exported to Poland must have Polish language labels and instruction manuals. For further information, please contact the U.S. Department of Commerce Foreign Commercial Service office in Warsaw for further details: http://www.buyusa.gov/poland/en/.

Conclusion

The addition of eight Central and Eastern European countries to the European Union expands the geographic scope of the CE Marking regime. U.S. exporters who understand and comply with the CE marking requirements will find an easier path to successful exporting. This report provides a much needed overview of the CE marking requirements that U.S. companies face in an enlarged European Union.

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